Quarterly Progress Report

N01-NS-1-2333

Restoration of Hand and Arm Function by Functional Neuromuscular Stimulation

Period covered: October 1, 2003 to December 31, 2003

Principal Investigator: Robert F. Kirsch, Ph.D.

Co-Investigators:

Patrick E. Crago, Ph.D.
P. Hunter Peckham, Ph.D.
Warren M. Grill, Ph.D.
J. Thomas Mortimer, Ph.D.
Kevin L. Kilgore, Ph.D.
Michael W. Keith, M.D.
David L. Wilson, Ph.D.
Dawn Taylor, Ph.D.
Joseph M. Mansour, Ph.D.
Jeffrey L. Duerk, Ph.D.
Wyatt S. Newman, Ph.D.
Harry Hoyen, M.D.
John Chae, M.D.
Jonathon S. Lewin, M.D.
Dustin Tyler, Ph.D.

Program Manager: William D. Memberg, M.S.

Case Western Reserve University
Wickenden 407
10900 Euclid Avenue
Cleveland, OH 44106-7207
216-368-3158 (voice)
216-368-4969 (FAX)
rfk3@po.cwru.edu

Contract abstract

The overall goal of this contract is to provide virtually all individuals with a cervical level spinal cord injury, regardless of injury level and extent, with the opportunity to gain additional useful function through the use of FNS and complementary surgical techniques. Specifically, we will expand our applications to include individuals with high tetraplegia (C1-C4), low tetraplegia (C7), and incomplete injuries. We will also extend and enhance the performance provided to the existing C5-C6 group by using improved electrode technology for some muscles and by combining several upper extremity functions into a single neuroprosthesis. The new technologies that we will develop and implement in this proposal are: the use of nerve cuffs for complete activation in high tetraplegia, the use of current steering in nerve cuffs, imaging-based assessment of maximum muscle forces, denervation, and volume activated by electrodes, multiple degree-of-freedom control, the use of dual implants, new neurotization surgeries for the reversal of denervation, new muscle transfer surgeries for high tetraplegia, and an improved forward dynamic model of the shoulder and elbow. During this contract period, all proposed neuroprostheses will come to fruition as clinically deployed and fully evaluated demonstrations.

Summary of activities during this reporting period

The following activities are described in this report:

- *Computer-based modeling of selective stimulation of the radial nerve*
- *Wireless data acquisition module for use with a neuroprosthesis.*
- *Rapid prototyping and real-time control for functional electrical stimulation (FES)*
- *An implanted neuroprosthesis for electrical stimulation through nerve- and muscle-based electrodes and myoelectric recording*
- *Proportional myoelectric control strategy for low cervical tetraplegia*

Computer-based Modeling of Selective Stimulation of the Radial Nerve

Contract section:
E.1.a.i Achieving Complete and Selective Activation Via Nerve Cuff Electrodes

Introduction

The development plan for advanced upper extremity neuroprostheses includes the implementation of multi-contact nerve cuff electrodes. These electrodes are being used to activate selectively multiple muscles from a proximal nerve trunk. To maximize the probability of successful selective activation, a number of background studies were made. First, a study of the nerve branch-free lengths and nerve diameters were obtained by post-mortem dissection of six human brachial plexuses, and the results were used to identify candidate implantation sites. Second, topographic mapping of the fascicular structure of upper extremity nerves was undertaken. A method was developed to enhance the diffusion of fluorescent lipophilic dyes, and enable these dyes to be used to trace targeted muscle branches to the proximal nerve trunk. Comparison of maps across a population of nerves will allow identification of common nerve topography and further refine implant site selection. Further, these maps can be used to create anatomically accurate finite elemental models of nerve cuff electrode stimulation. These models will serve as predictors for the selective ability of the cuff electrodes, and be used to refine stimulation methods following nerve cuff implantation. In the past quarter we implemented a finite element model of the human radial nerve.

Model Development

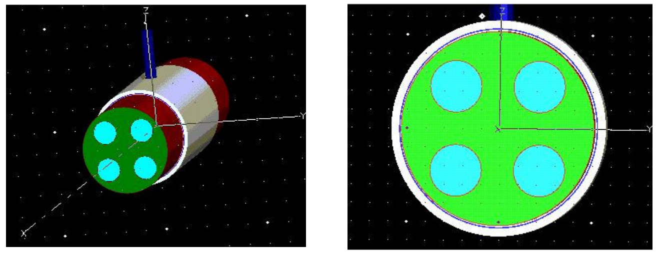
We implemented the model using the finite element software "Ansoft". The development included definition of the material properties and geometries, including incorporation of 2-dimensional topography based on prior fascicle mapping results, and implementation of a cuff around the nerve. At this stage, a simplified geometry was extruded into the third dimension, but methods to create anatomically realistic three-dimensional models await development.

The material conductivities used in the model are given in Table 1. A saline bath surrounded the nerve model, and the bath size was selected so that no aspect of the nerve model was closer then 2 cm from the bath boundary. The nerve circumference was always chosen to be circular. This is realistic as implantation of a cylindrical nerve cuff reshapes a nerve into a circular cross section. The circumference was chosen by estimating a center point on the actual cross-section used to create the model, and then calculating the distance to the nerve exterior around the nerve every 45 degrees. If the distances varied greatly, then the center point was adjusted until the variance between the eight distances was minimized. Once this was accomplished the radius of the circular model was determined by taking the average of the eight distances. The thickness of the perineurium surrounding the entire nerve and the individual fascicles was chosen as 30 μm.

Model Parameters	Conductivity (S/m)
Perineurium	6.28e-04
Epineurium	1.0
Tight Encapsulation	6.59e-02
Saline (0.9% NaCl)	2.0
Cuff (Silastic 4210)	1.00e-17
Fascicles (Transverse)	0.1
Fascicles (Longitudinal)	1.0

Table 1. Conductivities of Tissues and Materials

The cuff was a 300 μm thick layer of silicone rubber (Silastic 4210), 1.2 cm long. A series of layers were modeled between the cuff and the nerve including a 50 μm thick layer of saline between the cuff and the tight encapsulation layer, and a 50 μm thick layer of tight encapsulation tissue between the saline layer and the epineurium. Four platinum electrodes, modeled as cylindrical discs that had a 0.35 mm radius and a 200 μm thickness, were positioned in middle of the cuff 90 degrees apart, and the stainless steel lead wires were modeled as a 1.0 mm diameter, 1 cm long cylinder positioned 20 μm into the silicone cuff and extending out towards the boundary of the saline bath (Figure 1). This served as the return electrode for the model.

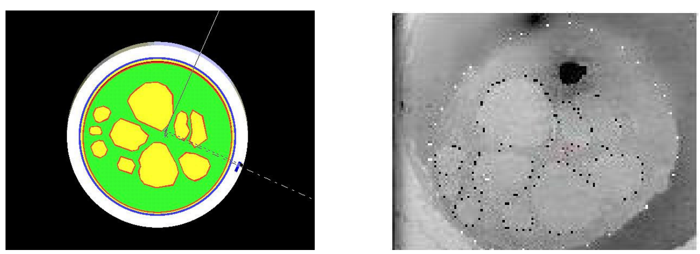


A **B**

Figure 1. A. View of cuff electrode model around a generic nerve topography. **B.** Cross-section of same model.

The cuff model can be translated along and rotated around the nerve model so that different stimulation cases can be studied. Any of the platinum electrodes can serve as the active electrode with the electrode lead serving as the return electrode. In a case where field steering is modeled, the return electrode can be changed to the appropriate platinum electrode.

We have successfully implemented a 2-dimensional recreation of a real nerve cross-section in the model, and this model is shown alongside the original cross-section in Figure 2.



A **B**

Figure 2. A. Shows the side view of the constructed model **B.** Shows the original cross-section which was the basis for the model.

To simplify the model, and to replicate what is expected following implantation of cylindrical cuff electrodes, the outer circumference of the nerve model was assumed to be circular. To replicate the fascicular geometry, the original cross section was magnified so that the perineurium of each fascicle was identifiable, and the perimeter of each fascicle was represented as a series of connected straight lines to reduce the complexity of the model and subsequent computation time. This model demonstrates that an accurate representation of a complicated fascicular geometry can be implemented.

Wireless Data Acquisition Module for Use with a Neuroprosthesis

***Contract section**:* E.1.a.v Sensory feedback of contact and grasp force

Abstract

A general wireless data acquisition module (WDAM) is being developed for use with a neuroprosthesis. The WDAM is intended to be used with sensors such as the shoulder or wrist position transducer, finger-mounted joysticks, or remote on-off switches. Currently these sensors are connected to a controller via cables, which are cosmetically unappealing to the user and often get caught on wheelchairs, causing them to be damaged. Switch-activated transmitters mounted on walkers have been used previously in FES applications [1]. Recent advances in wireless technology have reduced the complexity and size of the wireless circuitry and have increased the likelihood that a small, low power, reliable wireless link could be assembled from commercially available components.

Methods

In the previous progress report, three different software protocols were evaluated for the prototype WDAM circuit. The prototype circuit included the transceiver, microcontroller, power regulator and buffer/amplifier components. In this quarter, battery longevity tests were performed. Since the longevity of a battery is dependent on several variables, it is difficult to determine from a manufacturer's specifications how a battery will perform under specific conditions. Three different types of primary (replaceable) coin cell batteries (lithium, silver oxide, and zinc air) were tested (Table 2). Each of these battery types was used to power a sensor module.

The modules were programmed to use a master/slave protocol. In this protocol, the central module (the 'master') requests data from a sensor module (the 'slave') and then waits for a reply. The sensor module listens for a data request. When it detects an appropriate request, it samples data, then forms and transmits a packet, then goes back to listening for other requests. Upon receiving the data packet, the central module determines if it was received properly. If it was not received properly, the data request is sent again. If the data was received properly, or if it was not received properly after four attempts, the central module moves on to the next data request. The central module requested data continuously at a 20 Hz rate. For these experiments, data that was properly received by the central module was sent via a serial port to a desktop computer that was running a LabView data logging program.

The length of time that the sensor module was able to successfully transmit data was recorded for each battery type (Table 2).

Table 2. Wireless Data Acquisition Module Battery Tests

Battery Type	Brand	Model	Size (Diam. x Ht.) (mm)	Rated Capacity (mA-hr)	Starting Voltage (V)	Ending Voltage (V)	Current Draw (mA)	Running Time (hrs)	Actual Capacity (mA-hrs)
Zinc Air	Energizer	675	11.6 x 5.4	600	1.4	0.6	8.2	**74.1**	608
Lithium	Energizer	2032	20.0 x 3.2	225	3.2	0.9	3.0	**40.9**	123
Silver Oxide	Duracell	76S	11.6 x 5.3	175	1.6	0.1	6.3	**28.6**	180

Results

The zinc air and silver oxide batteries required more current than the lithium cell since their nominal voltage is less than half of the 3.3 volts required by the circuit. The power regulator boosts the voltage to the necessary level, but this process requires more current. However, even with the higher current, the zinc air battery lasted the longest (74.1 hours). The similar-sized silver oxide battery had the shortest running time (28.6 hours). This was not surprising since it had the lowest rated capacity (current times running time, in mA-hrs) of the three batteries types tested. Both the zinc air and silver oxide batteries' actual capacities were very close to their rated capacities (Table 2).

The lithium battery had the lowest current draw, since its nominal voltage was close to what the circuit needed. Although it produced the second longest running time (40.9 hours), it had the shortest actual capacity. This capacity was only 55% of the rated capacity, probably because this battery is intended for applications with lower current requirements.

A review of upper extremity neuroprosthesis usage times indicates that frequent users of the systems activate the neuroprosthesis for less than two hours a day. At this usage rate, the zinc air and lithium batteries would last for several weeks before needing to be replaced. In addition, as shown in last quarter's progress report, there are other methods of reducing the current draw for the circuit, such as utilizing protocols that put the transceiver to "sleep" for brief periods, and/or using transceivers with faster communication rates. Thus, it appears that the wireless data acquisition module will be able to operate for an acceptable period of time using a single coin cell battery. The selection of the zinc air or lithium battery will be made at a later time, when some of the practical issues related to packaging and the ease of battery replacement are resolved.

Next Quarter

In the next quarter, a printed circuit board version of the WDAM will be fabricated. The board layout has been started and the circuit components have been ordered. It is likely that this circuit board will increase the acknowledgement rate and decrease the re-transmission rate for the WDAM, since it is likely that many of the transmission errors are due to noise that is picked up from the soldered wires that are used in the prototype circuit.

Once the printed circuit board is fabricated, the faster transceiver modules will be evaluated. The higher data rates will allow the transceiver to spend more time in sleep mode, and therefore will reduce the power requirement further.

References

[1] Z. Matjacic, M. Munih, T. Bajd, A. Kralj, H. Benko, and P. Obreza, "Wireless control of functional electrical stimulation systems," *Artif Organs*, vol. 21, pp. 197-200, 1997.

Rapid Prototyping and Real-Time Control for Functional Electrical Stimulation (FES)

Contract section:
E.1.a.vi. Implementation and Evaluation of Neuroprosthesis for High Tetraplegia

Abstract

In this project, we are developing a set of software and hardware tools to provide rapid prototyping and real-time control for FES systems. The abilities to read physiological data, process and make calculations based on those inputs, then adjust and communicate stimulation parameters at repeatable, well-defined time intervals are essential to control and develop algorithms for neuroprostheses. Typically, only computer engineers or programmers using C and/or assembly language have achieved such real-time control. This moves the development effort away from the researchers and/or clinicians that are directly studying the system. By using the much higher level and more abstract means of programming required for software packages from The MathWorks, Inc. (Natick, MA), we aim to put into the hands of these users, themselves, the abilities to quickly design, implement, test, revise and re-test ideas in real-time. Our tools will provide a general mechanism for studying FES-related problems, and development of application-specific solutions using these tools will be left to individual researchers or clinicians. Therefore, we will be able to centralize the technology development and support for the core software and hardware that serve many projects in this contract. This reporting period represents the continued efforts at developing these tools. Described below is the development of a laboratory-based system for rapid prototyping of FES systems. This system utilizes the same hardware being used to develop a subject wearable, PC based, data acquisition and control system for prototyping FES systems. This laboratory-based system is being designed to be fabricated in small quantities (1-5).

Background

Until recently, hard real-time control of FES systems was typically realized using custom designed microprocessor-based systems. Software for these systems required intimate knowledge of the system architecture and was usually written in assembly language and/or cross-compiled C. Several years ago, The MathWorks Inc. (www.mathworks.com) introduced a series of software products that allow rapid prototyping of hard real-time systems using a block diagram based design input technique. The user of this rapid prototyping environment interconnects functional blocks from a block library in order to implement the desired system. These tools allow the system to be modeled and evaluated in a Windows environment. Once the user is satisfied with the results of the model, the system can be migrated to a real-time target.

A typical FES system is shown in Figure 3. The "Host Processor" provides a windows-based programming environment to develop FES applications. The "Target Processor" runs the FES applications in real-time. It also provides the interface(s) for various inputs and outputs. In order to provide rapid prototyping and real-time control, we use personal computers (PCs) running MathWorks software for the "Host" and "Target" processors, as described in Quarterly Progress Report #2 (QPR#2, July-Sept 2001).

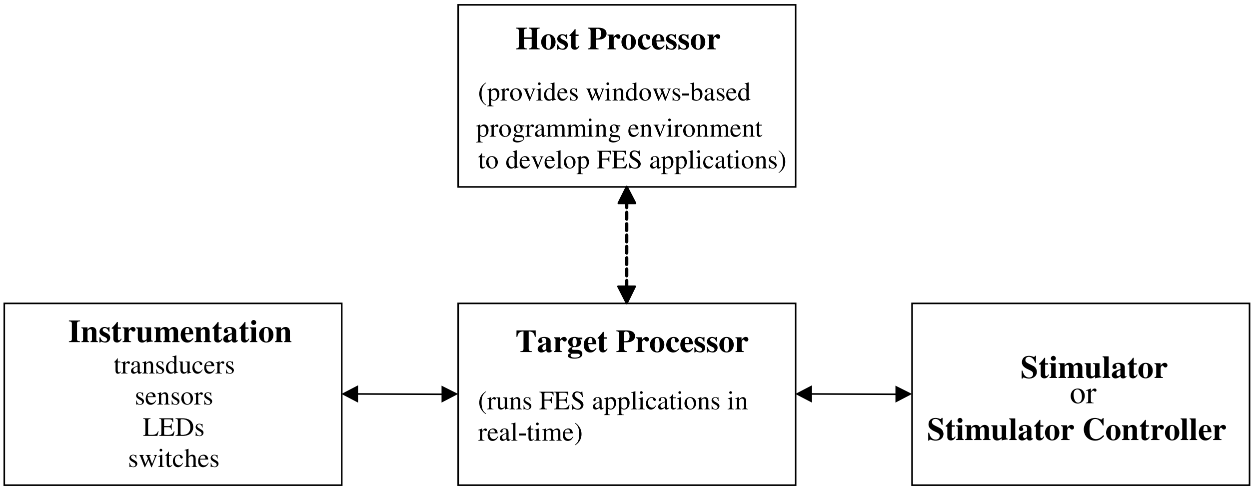


Figure 3. Basic structure of a Functional Electrical Simulation system. (The Host Processor may be present only initially to download the application, or it may always be required to control the Target Processor.)

The MathWorks tools allow us to develop real-time FES systems using their rapid prototyping environment. We began by using desktop PC-compatible hardware running xPC Target for control of stimulation systems that were connected to the target PC through a serial interface. These early systems controlled the stimulator on a pulse-by-pulse basis (see QPR#2, Jul-Sept 2001, & QPR#3, Oct-Dec 2001). We then replaced the desktop hardware with a single board computer (SBC) from Versalogic. At that time we also utilized the xPC Target Embedded Option that allows the target system to operate in a host independent, stand-alone mode. The functionality of our current upper extremity external control unit (NPS4) was modeled and realized on the SBC. Our recently developed Universal External Control Unit (UECU) was serially connected to the xPC Target to provide an interface to our IRS8 implantable stimulator (see QPR#8, Jan-Mar 2003).

The UECU is a custom designed modular system that can be configured for specific FES applications. The UECU provides a small, low power, application specific, external control unit. Major modules include; the Implant Control Module (ICM), that is capable of controlling two implantable stimulators (IRS8 and/or IST family devices), the Percutaneous Stimulator Module (PSM), that provides multichannel stimulus output for percutaneous electrodes, the Communications Module (CM), that provides high speed serial communications and low power consuming processing, and the System Module (SM), which manages user inputs, displays, and audio tones. These modules can be used in various combinations in order to meet the requirements of a particular FES application. The modules are housed in a small wearable enclosure (15x8x5 cm) that also contains a rechargeable battery and power management circuitry. Figure 4 shows a photograph of two differently configured UECUs.

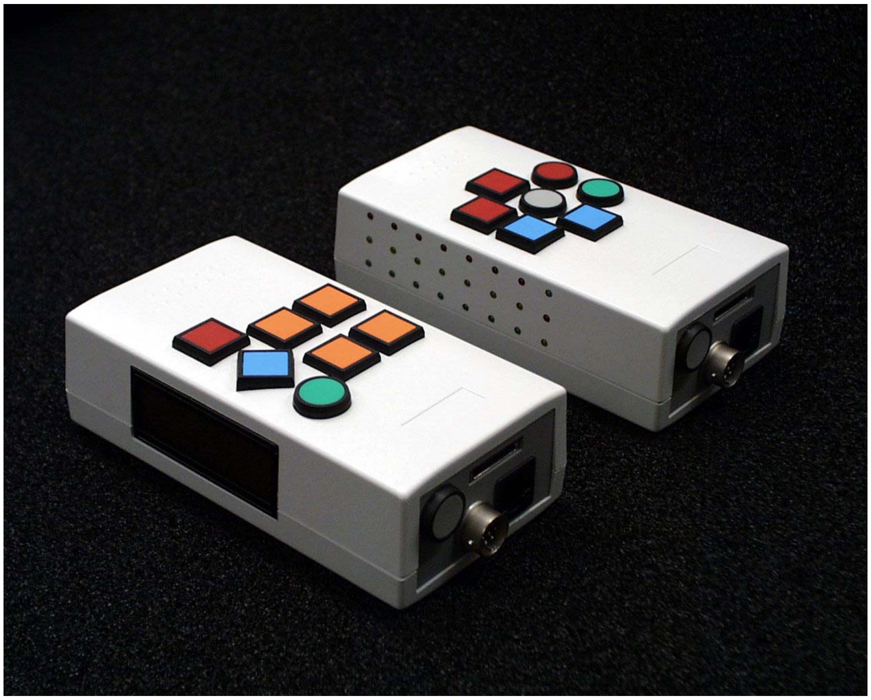


Figure 4. Two Different Configurations of the Universal External Control Unit (UECU).

Methods

As described in the Background section above, we have demonstrated the power of the MathWorks rapid prototyping environment as it applies to the development of non-mobile, lab based, FES systems. We are currently developing an xPC Target compatible, PC based, Wearable Data Acquisition and Control System (WDACS) that utilizes our UECU as the interface to various stimulators/telemeters. A bock diagram of this rapid prototyping environment is presented in Figure 5. This portable system will allow us to investigate unencumbered mobile applications, as well as being able to deploy proof-of-concept systems for operation in various user environments outside of the laboratory.

Referring to the block diagram shown in Figure 5, the "Host PC" provides a Windows environment for xPC Target program development and lab-based data acquisition (typically stationary instrumentation). The "Host PC" connects to the WDACS through an isolated serial interface. This communications interface is used to load the xPC Target application into the WDACS. Once the application is loaded, this serial interface can be disconnected or it may be used to monitor and control various application parameters within the WDACS.

The WDACS is connected to the UECU through the UECU's dedicated communication interface. This UECU interface provides the WDACS with access to our implantable, percutaneous, and/or surface stimulation systems. The UECU interface also provides the WDACS access to our implantable systems' transducers and sensors, as well as application specific user interfaces such as position transducers and finger switches. Through this interface the WDACS also has access to various UECU enclosure switches, displays, and the audio tone generator.

The WDACS provides additional data acquisition capabilities for supplemental user based instrumentation. Power for analog instrumentation is available from the WDACS.

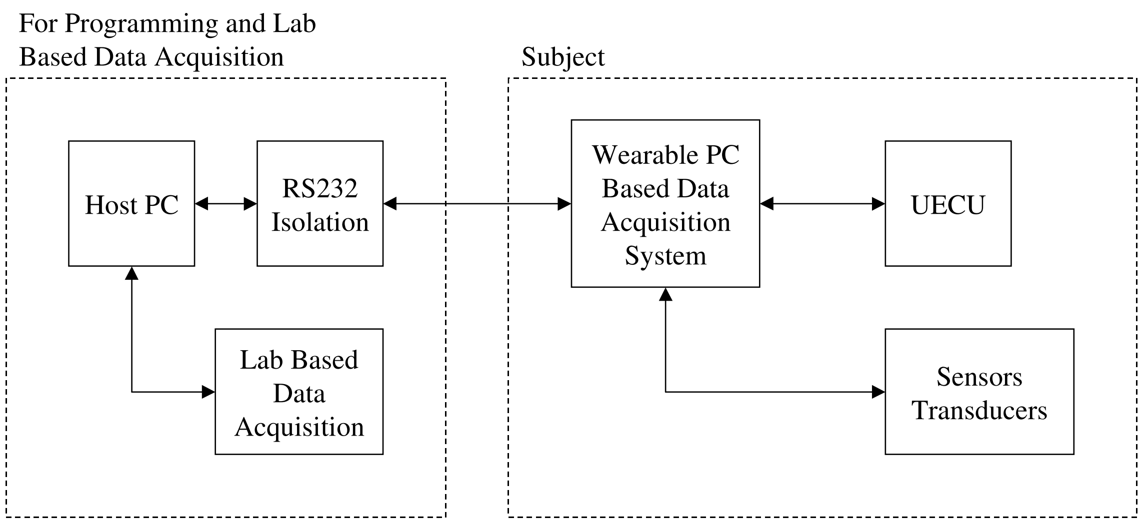


Figure 5. Block diagram of the proposed wearable data acquisition environment.

This WDACS will be comprised of a commercial off the shelf (COTS), industry standard, PC/104 single board computer, an in-house designed multifunction board, and user accessible batteries housed in a custom enclosure. We conducted a market survey of available PC/104 single board computers with data acquisition capabilities that meet the requirements imposed by a wearable system. The requirements include low power consumption and driver support from The MathWorks for xPC Target.

The Prometheus (model PR-Z32-EA-ST) from Diamond Systems Corporation (www.diamondsystems.com) is a highly integrated PC/104 CPU with data acquisition that meets the requirements and has been selected for the core of the system. The Prometheus Single Board Computer is realized on a single, industry standard, PC/104 printed circuit board, which measures 9 x 9.6 cm. A photograph of the Prometheus SBC is shown in Figure 6. Features of the Prometheus are summarized in Table 3.

Table 3. Features of the Prometheus Single Board Computer.

Pentium Class 486-DX2 Processor running at 100MHz with Co-Processor
32MB SDRAM System Memory
32MB Solid State FlashDisk
4 Serial Ports
2 Powered USB Ports
100BaseT Ethernet (100Mbps)
16 Channel, 16-bit Resolution, 100KHz (aggregate) ADC
Programmable Input Ranges/Gains
4 Channel, 12-bit DAC
24 Programmable Digital I/O
2 Programmable Timers
Programmable Gate and Count Enable

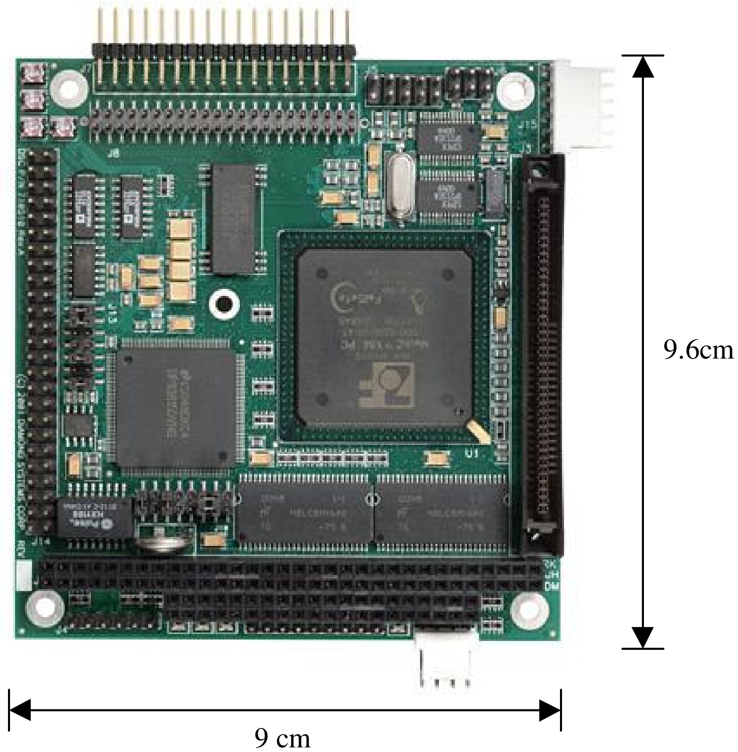


Figure 6. Diamond Systems Prometheus Single Board Computer

Results

The proposed work consist of two major phases; enhancement of the Prometheus Development Kit for use with the MathWorks xPC Target tools in a lab environment, and design and fabrication of the Wearable Data Acquisition and Control System. Experience with the enhanced development kit will help to finalize the design of the wearable system.

The Prometheus Development Kit

A Diamond Systems Prometheus Development Kit (CPR-Z32-EA-DK) was purchased to evaluate the functionality of the Prometheus SBC. The Prometheus Development Kit (PDK) provides everything needed to configure the Prometheus SBC with a keyboard, mouse, and display, and is housed in a 14.0 x 14.5 x 7.6 cm enclosure. A single 5V power supply provides all the necessary power. The kit also provides all of the connectors for interfacing with various peripheral devices. The features of the Prometheus Development Kit are given in Table 4.

The PDK is being enhanced to include a floppy drive for initial loading of the xPC Target applications. The system is also being enhanced with a data acquisition interface for laboratory use. A block diagram of the Enhanced PDK is shown in Figure 7.

Table 4. Prometheus Development Kit.

PR-Z32 EA Prometheus PC/104 CPU
PNL-Z32 Panel I/O Board
PB-Z32-300 Pandora 3" Enclosure
FD-32 32MB FlashDisk Module
ACC-IDEEXT FlashDisk / IDE Extender Board
PC/104 VGA Board
C-PRZ-Kit Prometheus Cable Kit
120VAC wall adapter
All Mounting Hardware
User Documentation
Utility Software

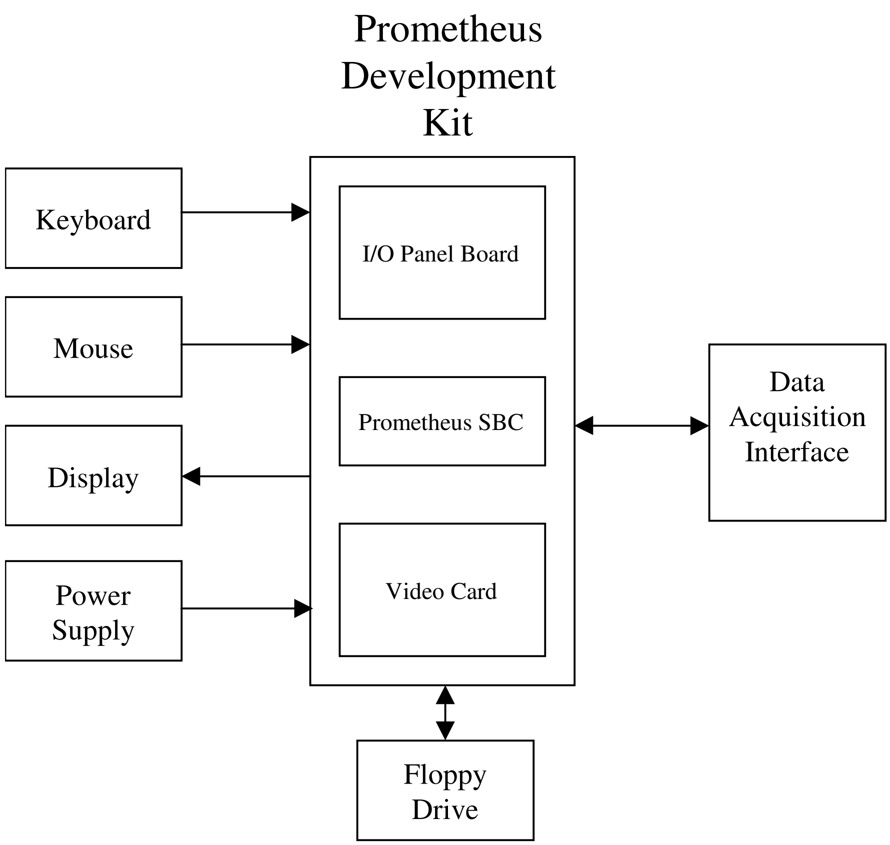


Figure 7. Enhanced Prometheus Development Kit.

The data acquisition interface is being fabricated to allow connection of lab-based instrumentation to the PDK. This interface provides BNC connectors for connecting to the ADC, DAC, counter/timer control, and digital input/output. In addition, the interface houses 4 potentiometers, 4 toggle switches, 4 pushbutton switches, and 8 LEDs that can be conveniently connected to the appropriate PDK data acquisition subsystem. The interface also contains a power supply. A block diagram of the data acquisition interface is presented in Figure 8.

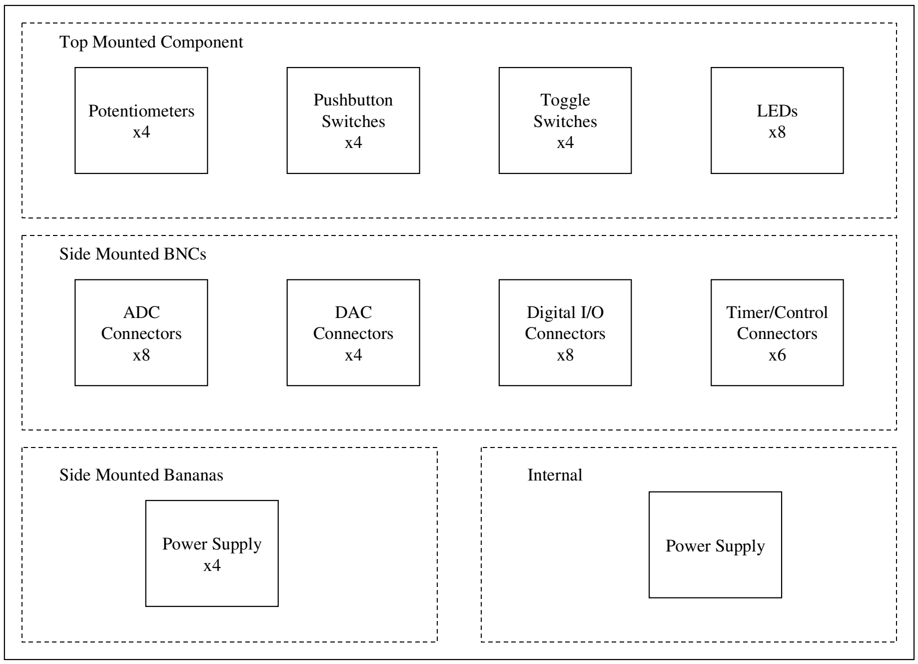


Figure 8. Block diagram of the PDK data acquisition interface box.

Physically, the PDK, the floppy drive, and the data acquisition interface are housed in a single 25.5 x 14.5 x 14 cm enclosure available from Diamond Systems.

The Wearable Data Acquisition and Control System

The second phase of the project is the development of the Wearable Data Acquisition and Control System (WDACS). The WDACS is based upon the Diamond Systems Prometheus SBC. The Prometheus Single Board Computer is realized on a single, industry standard, PC/104 printed circuit board, which measures 9 x 9.6 cm. The PC/104 bus is based on a mezzanine bus connector scheme with a 1.5 cm board-to-board height profile. We have identified an enclosure, which measures 12.9 x 13.3 x 3.8 cm, which will house the SBC, a multifunction board, and various connectors, switches, and displays. Two Sony rechargeable Li Ion batteries (NP-F550) will clip on to the front of the enclosure increasing the height of the system to 6.7 cm. This is similar in size to one of our current portable stimulators (V40) used in various lower extremity applications. The user accessible batteries simplify the design of the power system because a commercially available battery charger can be used to independently and safely recharge the batteries while allowing the user to use fully charged battery packs as necessary. This approach has also been successfully used on the above-mentioned portable stimulator.

Next Quarter

We will complete the fabrication of the data acquisition interface for the Prometheus Development Kit. The next step will be to determine how to interface the Host computer to the PDK through either an isolated serial connection or an isolated network connection. This will alleviate the need for the floppy disk drive, which will not be available on the wearable system. It is anticipated that both the PDK and wearable system will be connected to the Host via this interface when it is necessary to update the application software, and also to access data for system analysis.

We will continue the design and development effort of the Wearable Data Acquisition System. Experience with the use of the PDK will help to refine the appropriate functionality and configuration of the WDACS. We will determine the laboratory and user interfaces, i.e. connectors, switches, displays, etc. We will also determine and design any application specific circuitry for support of transducers and sensors, as well as the dedicated interface to the UECU.

An Implanted Neuroprosthesis For Electrical Stimulation through Nerve- and Muscle-based Electrodes and Myoelectric Recording

Contract section:

E.1.a.vi Implementation and evaluation of neuroprostheses for high tetraplegia

Introduction

The goal of this section of the project is to develop the hardware components necessary to implement advanced neuroprostheses for high tetraplegia. The key component of this effort is the development of an implanted stimulator/telemeter device that is capable of both electrical stimulation and myoelectric recording. Specifically, we are designing and fabricating an implanted neuroprosthesis capable of 12 channels of stimulation and has two channels of myoelectric signal (MES) recording, referred to as the implantable stimulator-telemeter-12 (IST-12). The myoelectric signal recording has been successfully demonstrated in-vivo, and is now being implemented with human subjects (in a separate project). With this phase of development completed, we are now addressing the specific stimulation capabilities of this device needed for this contract. Specifically, the device must be capable of safely and effectively delivering stimulus parameters appropriate for stimulation using muscle-based electrodes **and** nerve-based electrodes. During this quarter, we have completed the circuit modifications and performed our first in-vivo test of this modification.

Methods

The first generation of the IST-12 device was designed and built for stimulation via "muscle-based" electrodes. These electrodes are placed in or on the target muscle and produce muscle contraction through activation of the distal portion of the peripheral nerves. Two styles of "muscle-based" electrodes have been successfully used with all of our implanted upper and lower extremity neuroprostheses to date: 1) epimysial electrodes, which are sewn onto the muscle epimysium and 2) intramuscular electrodes, which are placed within the muscle belly. The typical stimulus parameters required for these electrodes is a constant current cathodic pulse with a pulsewidth selectable from 1 μsecond to 200 μseconds followed by a nominal 0.5 mA, current limited, charge-balanced anodic "recharge" phase. The IST-12 is capable of delivering eight discrete levels of cathodic current from 2.5 mA to 20 mA in 2.5 mA steps. In practice, however current levels less than 20 mA were rarely used for muscle-based electrodes.

In order to implement an implanted neuroprosthesis for high tetraplegia, it is necessary to activate some of the upper extremity nerves directly using "nerve-based" electrodes. In this project we will be using nerve cuff electrodes which wrap around the nerve. Nerve cuff stimulation uses much lower currents than epimysial or intramuscular electrodes, typically at least one order of magnitude lower. Not only are the currents lower, but the surface area of the electrodes in a nerve cuff are much smaller than epimysial or intramuscular electrodes. The existing design of the IST-12 implant cannot be used with nerve cuff electrodes due to two important design issues. **First**, the design of the stimulus output stage was such that, when an electrode on one channel delivers a cathodic pulse, a small (less than 0.5 mA) amount of current passes through the all other electrodes. This small anodic current at each electrode during the cathodic phases of the other electrodes was well below the threshold for muscle-based activation and was not a concern. However, this small amount of current is potentially sufficient to activate nerves through nerve-based electrodes. In practice, this would result in activation at every nerve electrode whenever a muscle-based electrode was activated. The **second** design issue is that nerve-based electrodes require activation below 2.5mA if graded activation is to be achieved. Therefore, it is necessary to design the IST-12 to be able to produce stimulus amplitudes that are in the range of 100μA – 2mA, well below the existing output capabilities.

Design Modifications

To address the issue of anodic current appearing on other electrodes while an electrode is delivering a cathodic pulse, the following modification was developed. The current path of this anodic current was modified to be an "open circuit" during the cathodic phase of any stimulus channel and then closed at the end of the cathodic pulse. This eliminates the possibility of the other electrodes acting as anodes when one electrode is cathodic. When multiple channels are being stimulated, this modification will cause the <0.5 mA anodic recharge to be discontinuous if stimulus channels are spaced close enough in time that one channel is still recharging when a different channel begins stimulation. It will also delay the total recharge time by the cathodic duration of other channels. This delay is expected to have only minor impact on the functional use of the neuroprosthesis, primarily related to a slightly reduced artifact-free period during which EMG signals can be recorded during stimulation.

To decrease the current levels to currents that will be more appropriate for nerve stimulation we have changed the value of four resistors in the implant. These four resistors inversely scale the cathodic stimulus current levels that the implant can deliver. The anodic recharge phase will remain current limited at 0.5 mA.

Results

An initial in-vivo test of the interrupted recharge design change was performed. The results showed clearly that activation of nerve-based electrodes did occur during recharge using the previous IST-12 design. By implementing the interrupted recharge, the inadvertent activation was eliminated. Further testing of this modification will be performed to confirm these results prior to finalizing the layout for the modified IST-12 circuit.

Conclusion

Two new features are necessary for implanted neuroprosthetic systems in order to implement systems for high tetraplegia. The first, myoelectric signal recording, has been successfully added to the implant design and is now in human use. The second, mixed muscle- and nerve-based stimulation outputs is now being addressed. A new modification to the circuit has been proposed and tested in animals. This modification appears to meet the design specifications. Finalization of the circuit layout and fabrication of devices will be pursued in the future.

Proportional Myoelectric Control Strategy for Low Cervical Tetraplegia

Contract section: E.1.b Control of Grasp Release in Lower Level Tetraplegia

Abstract

The purpose of this research is to develop and evaluate an advanced neuroprosthesis (NP) to restore hand function in persons with C7 (OCu:5 to OCu:7) level injuries. Through this work we will implement in human subjects a control methodology utilizing myoelectric signals (MES) from muscles that can act in synergy with hand function to govern the activation of paralyzed, electrically stimulatable muscles of the forearm and hand. This work encompasses the following objectives:

1) Characterize the MES recorded from a pair of muscles synergistic to hand function, demonstrating that the signals are suitable for NP control.
2) Demonstrate the ability of subjects to use different control algorithm options to perform simulated NP functions and to control a virtual hand.
3) Implement myoelectric control of the hand grasp NP in subjects with C7 spinal cord injury and evaluate hand performance.

Progress Report

The work this quarter focused on developing alternative myoelectric control strategies and programming them into our computer interface. The interface allows us to test the ability of subjects to modulate a command signal using different control strategies.

Previous work revealed advantages and limitations of a state control strategy where neuroprosthesis states were activated when particular patterns of MES activity were present in the wrist flexor and extensor. One of the limitations found was that in lightweight tasks that required little wrist flexion or extension, insufficient myoelectric activity was produced to bring about appropriate stimulation modulation. The result was that the stimulation remained constant during the task instead of appropriately opening and closing the hand. For a subject who could do lightweight tasks volitionally, the stimulation hindered his ability and essentially got in his way. Alternative myoelectric control strategies have been developed to address this limitation.

Proportional Control

We have programmed and begun testing a control strategy (Figure 9) in which the command signal (which modulates hand opening and closing) is directly proportional to the difference in processed MES of the wrist flexor (FCR) and extensor (ECRB). The command signal changes when the difference in MES changes as the wrist is flexed and extended. This strategy has the potential to give the user finer control of the neuroprosthesis by making the system feel more responsive and less mechanical than with a state control strategy. This proportional strategy may better enable quicker hand opening/closing and grip adjustments for lightweight tasks, which require little wrist action. Even small wrist actions will result in some command modulation (Figure 10a). Furthermore, during heavy tasks or other tasks where the motion of the wrist is restricted, the user will still be able to modulate the stimulation because the control strategy does not require wrist motion, only changes in MES (Figure 10b).

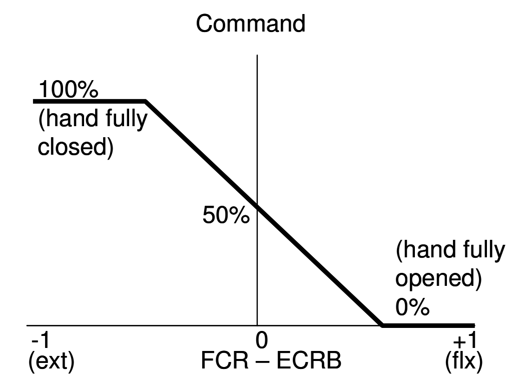


Figure 9. Proportional myoelectric control strategy

The Command Matching Test (see QPR #6, Jul-Sept 2002) was performed with an able-bodied subject using the MES difference between +/- 0.3 MES units as the command signal. Surface electrodes over the FCR and ECRB were used to record MES signals. The purpose of this test was to evaluate the ability of the subject to use the control strategy to modulate a command signal by matching and maintaining target command levels. The target command levels were presented on the computer screen along with a simulated hand that opened and closed in accordance with the control strategy. The subject was able to maintain the target command levels with a fluctuation in command of about 20% (Figure 11a). This may be adequate for tasks that require quick and brief periods of opening and closing, but may not be acceptable for tasks that require constant prolonged grasps.

The relatively large fluctuation in command signal (Figure 11a) indicates the need for a command lock, which is often required when using proportional control strategies. A command lock would allow the user to maintain a steady command level (grip posture or force) without having to maintain a muscle contraction, allowing users to perform tasks that require a constant grasp for a prolonged period of time (such as writing or holding a leash). A co-contraction command lock was implemented, and the Command Matching Test was repeated. The results (Figure 11b) are not an improvement on those obtained without the command lock and reflect the difficulty the subject had in co-contracting the muscles without disturbing the command signal.

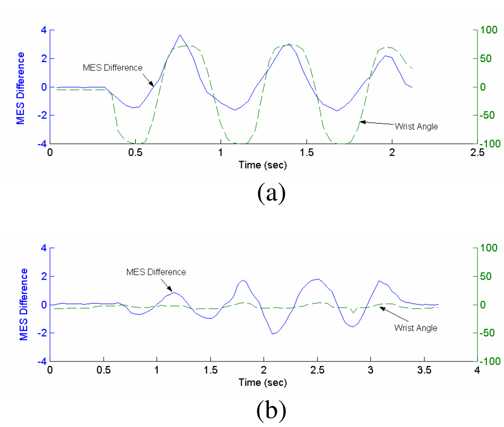


Figure 10. MES recorded with surface electrodes over ECRB and FCR. Wrist angle recorded with Penny and Giles® joint angle transducer. (a) Wrist flexion and extension produces a change in MES difference (FCR-ECRB). (b) Command modulation is possible when wrist motion is restricted.

An alternative command lock strategy is to have the lock engage automatically when the command level is maintained within a specified command range for a certain duration of time (inactivity lock) and to unlock the command by producing a large MES transient. This command lock strategy was used during a third Command Matching Test. The command lock automatically engaged when the command signal remained within 20% for 2 seconds and was disengaged by an MES transient that exceeded 1.0 normalized MES units (where 1.0 corresponded roughly to the maximum sustained contraction level). After disengaging the command lock, proportional control was restored to the user when the command level matched the level where the lock had been previously engaged. This was to prevent the transient unlock MES from causing a large command disturbance. The results (Figure 11c) using the automatic lock were superior to those obtained both when no lock was used (Figure 11a) and when the co-contraction lock strategy was used (Figure 11b).

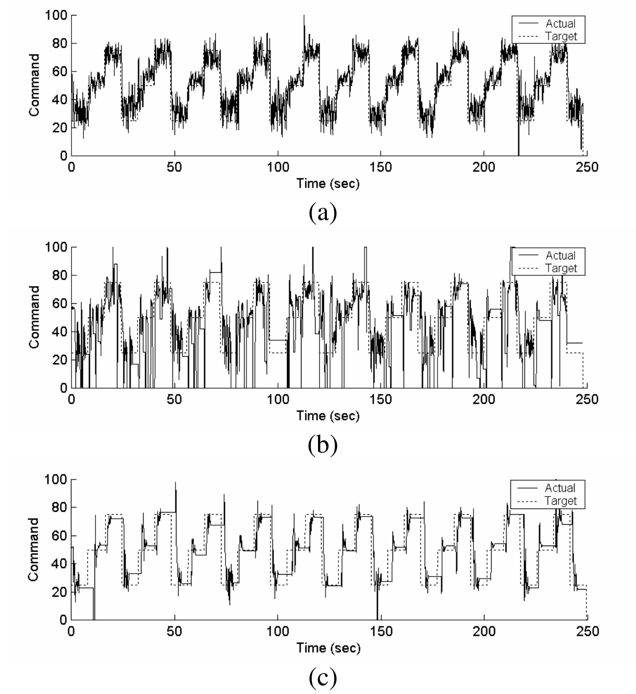


Figure 11. Results from Position Matching Test trials performed using the MES difference as a proportional command signal. (a) No command lock strategy. (b) Co-contraction command lock was used. (c) Command lock automatically engaged when command signal remained within 20% for 2 seconds and was disengaged by a large and brief ECRB contraction.

The proportional myoelectric control strategy described in this section will be implemented and compared to the state control strategy described in previous QPRs. It is expected that performance on the Command Matching Test with the state control strategy will be superior to that with the proportional control strategy, but that in actual hand tasks the proportional control strategy will provide a greater sense of control, enable hand grasp adjustments without making large wrist motions, and may improve performance in the grasp-release test.

Next Quarter

Additional alternative myoelectric control strategies are being developed. We are prepared to proceed with an implanted FES system with myoelectric control. We are actively seeking suitable candidates for this study.